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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/886,954	06/21/2001	Maureen J. Charron	96700/667	6743

7590 10/05/2004

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EXAMINER	
NICKOL, GARY B	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 10/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/886,954	CHARRON ET AL.	
	Examiner	Art Unit	
	Gary B. Nickol Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-11 and 14-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-11 and 14-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Re: Charron *et al.*

Date of priority: June 21, 2001

Request for Continued Examination

The request filed on 08-03-2004 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/886954 is acceptable and a RCE has been established. An action on the RCE follows.

The previously un-entered amendment filed 06-03-2004 has now been entered.

Claims 1, 4-11, 14-20 are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4-11, and 14-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 4-11, and 14-20 are indefinite for reciting using at least one nucleic acid probe which "hybridizes" to nucleic acid encoding GLUTx protein. The term "hybridizes" is indefinite because it assumes hybridization under any laboratory conditions, such as low, medium, or high

stringency. Furthermore, the specification (page 13) does not define the conditions essential for optimum hybridization. Thus, the conditions for hybridization read on any range of hybridization; that is, from very permissive to very high stringency. Hence, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention and would not be able to determine the metes and bounds of the claims.

Claims 1, 4-5, 8-11, 14-15, 18-20 are further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case only sets forth assaying a diagnostic sample comprising an antibody that reacts with the GLUTx protein of SEQ ID NO:1 and therefore the written description is not commensurate in scope with the claims drawn to using at least one nucleic acid probe which hybridizes to nucleic acid encoding GLUTx protein or any and all *agents* that react with GLUTx. The claims are broadly inclusive of naturally occurring DNA (i.e. variants, fragments, portions of unrelated genes) that hybridize to a nucleic acid encoding GLUTx protein.

Although the claims are drawn to using at least one nucleic acid probe which hybridizes to a nucleic acid encoding the GLUTx protein, the specification fails to sufficiently describe the genus of unrelated complementary nucleic acids that also recognize nucleic acids encoding GLUTx. . For example, the specification teaches (page 12) that the nucleic acid probes used in the present invention may be DNA or RNA, and may vary in length from about 8 nucleotides to the entire length of the GLUTx nucleic acid. Furthermore, the GLUTx nucleic acid used in the probes may be derived from mammalian GLUTX. Thus, there is no specific limitation of

nucleic probes that hybridize to nucleic acids encoding GLUTx. Hence, the claims are inclusive of nucleic acids that have the potential to hybridize and thus the claims encompass a broad genus of nucleic acids that are unrelated to nucleic acids that encode GLUTx. Furthermore, the conditions under which hybridization takes place have not been defined. Thus, the conditions for hybridization read on any range of hybridization; that is, from very permissive to very high stringency.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity. Further, there is no identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of potentially complementary nucleic acids, and therefore

conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. Applicants should further refer to Example 9 of the revised interim Written Description Guidelines regarding hybridization language (see http://www.uspto.gov/web/menu/written.pdf).

Further, with regard to the broad scope of any and all agents that react with GLUTx, the specification only appears to provide a written description of antibodies reactive to the GLUTx protein. The specification teaches (page 11) that an "agent" is inclusive of *any* molecule including "protein, polypeptide, peptide, nucleic acid (including DNA or RNA), antibody, Fab fragment, $F(ab')_2$, fragment, molecule, compound, antibiotic, drug, and any combinations thereof". However, in methods of determining defects in cell proliferation, the specification only provides adequate support for an antibody (page 37). One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only assaying a diagnostic sample comprising an antibody that reacts with the GLUTx protein of SEQ ID NO:1, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, and 4-7 are rejected under 35 U.S.C. 102(a) as being anticipated by Goldman *et al.* "Regulated Expression of the Novel Glucose Transport Facilitator, GLUTx1, in Proliferative Endometrium and Endometrial Adenocarcinoma" Abstract #5033, Proceedings of the American Association for Cancer Research, Vol. 42, March 2001.

For the purposes of comparing the claims to the prior art, it is assumed for examination purposes that the "proliferative endometrium" referred to in the prior art is equivalent to "non-diseased" endometrium as taught by the specification (page 9, para. 34).

Goldman *et al.* teach a method for determining whether a subject has a defect in cell proliferation, comprising assaying a diagnostic sample of the subject for GLUTx expression, wherein detection of GLUTx expression elevated above normal is diagnostic of a defect in cell proliferation, wherein the defect in cell proliferation is endometrial adenocarcinoma, and wherein the diagnostic sample is assayed using an antibody that is reactive with GLUTx protein. Absent evidence to the contrary, the GLUTx1 specific antisera used in the prior art would also be reactive with the claimed GLUTx1 protein of SEQ ID NO:1 as the specification appears to teach (page 1, line 33) that GLUTx and GLUTx1 are the same. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the

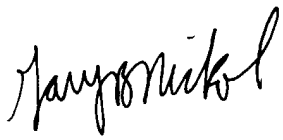
claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

All other rejections and or objections are withdrawn in view of applicant's amendments and arguments there to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-272-0835. The examiner can normally be reached on M-Th, 8:30-5:30; alternate Fri., 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



GARY NICKOL
PRIMARY EXAMINER

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Art Unit 1642